4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0315]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.8 With Standard for Exchange of Nonclinical Data Implementation Guide--Animal Rule Version 1.0; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the *Federal Register* on March 11, 2020. The document announced that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide--Animal Rule version 1.0 (SENDIG-AR v1.0) on March 15, 2020, and that these new standards will be required in submissions to FDA effective March 15, 2022. The document omitted the 36-month implementation period for certain investigational new drugs applications (INDs) as required by the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Standardized Study Data" which is referenced in that document. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 301-796-0035, email: cderdatastandards@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the *Federal Register* of March 11, 2020 (85 FR 14205), in FR Doc. 2020-04898, the following corrections are made:

1. On page 14205, in the second column, the first sentence of the SUMMARY is corrected to read: "The Food and Drug Administration (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide--Animal Rule version 1.0 (SENDIG-AR v1.0) on March 15, 2020, and that these new standards will be required in submissions for studies that start after March 15, 2022 (for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs)), and in submissions for studies that start after March 15, 2023 (for certain investigational new drug applications (INDs)), that are submitted to CDER."

2. On page 14206, in the first column, the last sentence of the document is corrected to read as follows: "FDA will begin supporting SDTM v1.8 and SENDIG-AR v1.0 on March 15, 2020, and the use of these new standards will be required in Animal Rule[1] submissions for studies that start after March 15, 2022 (for NDAs, ANDAs, and BLAs), and in Animal Rule submissions for studies that start after March 15, 2023 (for certain INDs), that are submitted to CDER."

Dated: June 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-12198 Filed: 6/9/2021 8:45 am; Publication Date: 6/10/2021]

[1] The Animal Rule refers to FDA's regulations for the approval of new drugs and biological products when human efficacy studies are not ethical or feasible (see 21 CFR 314.600-650 for drugs and 21 CFR 601.90-95 for biologics).